DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 18, 2017

C.R. Bard, Inc.
Henry Boland
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, UT 84116

Re: K110396
Trade/Device Name: Aspira® Peritoneal Drainage System
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: PNG
Dated: April 6, 2011
Received: April 8, 2011

Dear Henry Boland:

This letter corrects our substantially equivalent letter of May 6, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110396

Device Name: Aspira® Peritoneal Drainage System

Indications for Use:

The Aspira® Peritoneal Drainage System is indicated for intermittent drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites.

The Aspira® Drainage Bag is indicated for use only with the Aspira® Drainage Catheter for intermittent drainage.

The Aspira® Dressing Kit is indicated for dressing of a catheter and exit site.

The Aspira® Luer/Universal Adapter is intended to provide access to the Aspira® Drainage Catheter. It is used to drain fluid using standard wall suction, water seal drainage system, glass vacuum bottle, syringe or other appropriate method.

The Aspira® Valve Assembly attaches to the Aspira® Drainage Catheter. The Aspira® Repair Kit is for the repair of the Aspira® Drainage Catheter and replacement of the Aspira® Valve Assembly.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110396

MAY 6 2011

510(k) Summary
21 CFR 807.92

Aspira* Peritoneal Drainage System

General Provisions	Submitter Name: Submitter Address:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Henry Boland Regulatory Affairs Specialist henry.boland@crbard.com 801.522.5000 ext. 5428 801.522.5425 fax
	Date of Preparation:	9 February 2011
Subject Device	Trade Name:	**Aspira*** Peritoneal Drainage System
	Classification Name:	Peritoneal Dialysis System and Accessories 21 CFR 876.5630 - Class II FJS - Peritoneal dialysis system and accessories
Predicate Device	Trade Name:	**Aspira*** Peritoneal Drainage System
	Classification Name:	Peritoneal Dialysis System and Accessories 21 CFR 876.5630 - Class II FJS - Peritoneal dialysis system and accessories
	Premarket Notification:	K081288, concurrence date 18 July 2008
	Manufacturer:	Bard Access Systems, Inc.
Device Description	The **Aspira*** Peritoneal Drainage System provides patients with a convenient method to relieve malignant ascites symptoms at home. The primary components of the **Aspira*** Peritoneal Drainage System are the **Aspira*** Peritoneal Drainage Catheter and the **Aspira*** Drainage Bag. The **Aspira*** Peritoneal Drainage System.	
Intended Use	The **Aspira*** Peritoneal Drainage System is intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites.	
Indications for Use	The **Aspira*** Peritoneal Drainage System is indicated for intermittent drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites.	

The **Aspira*** Drainage Bag is indicated for use only with the **Aspira*** Drainage Catheter for intermittent drainage.

The **Aspira*** Dressing Kit is indicated for dressing of a catheter and exit site.

The **Aspira*** Luer/Universal Adapter is intended to provide access to the **Aspira*** Drainage Catheter. It is used to drain fluid using standard wall suction, water seal drainage system, glass vacuum bottle, syringe or other appropriate method.

The **Aspira*** Valve Assembly attaches to the **Aspira*** Drainage Catheter. The **Aspira*** Repair Kit is for the repair of the **Aspira*** Drainage Catheter and replacement of the **Aspira*** Valve Assembly.

Technological Characteristics

Technological characteristics of the subject **Aspira*** Peritoneal Drainage System are equivalent with respect to the basic catheter design and function to those of the predicate devices. Differences do not raise any new questions regarding safety and effectiveness.

Safety & Performance Tests

Verification and validation activities were designed and performed to demonstrate that the subject **Aspira*** Peritoneal Drainage System met predetermined performance specifications. The following guidance documents and standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

ISO 10993-1:2009	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
ISO 10993-7:2008	Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals
ISO 594-1:1986	Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1: General Requirements
ISO 594-2:1998	Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock Fittings
EN 1617:1997	Sterile Drainage Catheters and Accessory Devices for Single Use
EN 1618:1997	Catheters Other Than Intravascular Catheters - Test Methods for Common Properties
ISO 11607-1,2:2006	Packaging for Terminally Sterilized Medical Devices
ISTA -1G:2005	International Safe Transit Authority Procedure 1G
BS EN 550:1994	Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
ISO 11135-1:2007	Sterilization of health care products- Ethylene Oxide – Validation and Routine Control of Sterilization Processes for Medical Devices
AAMI TIR 19:1998	Guidance for ANSI/AAMI/ISO 10993-7:1995, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals - Replaces AAMI ST29 and AAMI ST30; Cited as relevant guidance to FDA-recognized standard ANSI/AAMI/ISO 10993-7

	The subject device met all pre-determined acceptance criteria and demonstrated substantial equivalence as compared to the predicate device.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, safety, and performance testing, the subject **Aspira*** Peritoneal Drainage System meets the pre-determined requirements under 21 CFR 820.30, Design Controls, and demonstrates that the subject device is substantially equivalent to the predicate device.

* Aspira is the trademark and/or registered trademark of C.R. Bard, Inc. or an affiliate.